

REMARKS

Reconsideration of the above-identified application in view of the amendment above the remarks below is respectfully requested.

Claim 4 has been canceled in this paper. Claims 1 and 43 have been amended in this paper. No new claims have been added in this paper. Therefore, claims 1-3, 5-31 and 35-44 are pending. Of these claims, claims 35-42 have been withdrawn as being directed at non-elected Groups. Therefore, claims 1-3, 5-31 and 43-44 are under active consideration.

Claims 1-31, 43 and 44 stand rejected under 35 U.S.C. 112, first paragraph, “as failing to comply with the written description requirement.” In support of the rejection, the Patent Office states the following:

The amendment to instant claims 1 and 43 to recite a further step of “outputting the conclusion to at least one of a display, a user, a readily accessible memory and a computer on a network” (see for example claim 1, lines 17 and 18) is acknowledged. It is further noted that applicants response filed 08/08/2007 did not specify any portion of the instant specification as support for the amendments made to the instant claims. Upon review, page 28, lines 14-25 of the specification, filed 06/15/2005, does provide support for computer systems that includes communication via an inter- or intranet connection for performing calculations (rows of analysis). However, this teaching does not provide adequate support for outputting the conclusion to at least one of a display, a user, a readily accessible memory and a computer on a network as recited in the instant claims. Specifically, the instant specification lacks support for outputting a result of the disclosed methods to a display, a user, or memory. As such, the above cited amendment to the claims presents new matter.

Claims 2-32 and 44 are also included under this rejection due to their dependence from claim 1 and 43.

Without acquiescing in the propriety of the rejection, Applicants have amended claims 1 and 43 in the manner suggested by the Patent Office. Support for this amendment may be found in paragraph [0088] of the published application. Accordingly, the subject rejection has been overcome and should be withdrawn.

Claims 1-31, 43 and 44 stand rejected under 35 U.S.C. 101 “because the claimed invention is directed to non-statutory subject matter.” In support of the rejection, the Patent Office states the following:

Claims 1-31, 43, and 44 are drawn to a process for determining the biological effect and/or activity of at least one pharmaceutical composition. The claimed process comprises the abstract steps of analyzing cytosine methylation at chosen DNA site, selecting differentially methylated sites in said chosen DNA sites to generate a knowledge base, and concluding from said knowledge base the biological effect and/or activity of said at least one drug and/or pharmaceutical composition and, therefore, involves the application of a judicial exception. Regarding inventions involving the application of a judicial exception, said application must be a practical application of the judicial exception that includes either a step of a physical transformation, or produces a useful, concrete, and tangible result (State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999))). In the instant claims, there is no step of physical transformation that results from said application of judicial exception, thus the Examiner must determine if said application of a judicial exception produces a useful, concrete, and tangible result.

The amendment to instant claims 1 and 43 to recite a further step of “outputting the conclusion to at least one of a display, a user, a readily accessible memory and a computer on a network” (see for example claim 1, lines 17 and 18) is acknowledged. However, the newly recited outputting step encompasses the embodiments wherein a result is only output to a computer (a computer on a network) or memory (readily accessible memory). Such embodiments,

encompassing results that remain only within a computer memory or merely transferred to another computer, are not communicated or made available to a practitioner in a real world context.

Applicants respectfully traverse the subject rejection. The Patent Office is apparently contending that the claimed method consists of only abstract steps and, therefore, involves the application of a judicial exception. The Patent Office is apparently further contending that the claimed method is not a practical application of a judicial exception because it does not involve a physical transformation or produce a useful, concrete or tangible result. Applicants respectfully disagree. The Patent Office's position is predicated on the notion that the claimed method does not involve a physical transformation. However, this is clearly incorrect since the claimed analyzing step, as exemplified by claim 9, may comprise a physical transformation.

Accordingly, for at least the above reasons, the subject rejection should be withdrawn.

Claims 1-11, 13-21, 23-26, 28 and 31 stand rejected under 35 U.S.C. 102(e)(2) "as being anticipated by Laird et al. (P/N 6,311,393 B1) in light of Klippel et al. (P/N 3,558,768)." In support of the rejection, the Patent Office essentially repeats its reasons of record.

Applicants respectfully traverse the subject rejection and respectfully submit that the Patent Office has misread Laird et al. For example, with respect to step (b) of the claimed method, the Patent Office states near the bottom of page 6 of the outstanding Office Action that "Laird et al. disclose methylation amounts in multiple samples are quantitatively determined based on reference to a control reaction (sample B) (see Laird et al., col. 5, lines 61-64) which reads on an unexposed sample and the analysis of methylation levels in a plurality of samples." However, this reading of

Laird et al. is incorrect and does not correspond to step (b) of the present claims for the following reasons: First of all, the cited text actually reads: "The methylation amounts in the nucleic acid sample are quantitatively based on reference to a control reaction for amount of input nucleic acid." The Patent Office is apparently taking the position that control reaction = unexposed sample, i.e., corresponds to Sample B of the second step of the claimed method. However, it should be noted that, in the cited passage, it is stated that the amount of DNA in the sample is determined, not that the amount of methylation is determined. In other words, step (c) is not carried out on this sample. This is confirmed at col. 11, lines 51-55, of Laird et al. Secondly, it should be noted that the Laird control reaction sample is exposed to a bisulfite solution and is, therefore, not an "unexposed" sample, as required by the present claims. This is confirmed in Laird et al. by Fig. 3 and by col. 16, lines 30-46.

Accordingly, for at least the above reasons, the subject rejection should be withdrawn.

Claims 1-11, 13-21, 23-26, 28, 31, 43 and 44 stand rejected under 35 U.S.C. 103(a) "as being unpatentable over Laird et al. (P/N 6,331,393 B1) in light of Klippel et al. (P/N 3,558,768) as applied to claims 1-11, 13-21, 23-26, 28, and 31 above, and further in view of Lorincz et al. (Molecular and Cellular Biology (2000) pages 842-850)."

Applicants respectfully traverse the subject rejection. Once again, Applicants respectfully submit that the Patent Office has erred in stating that Laird et al. determines methylation in an unexposed sample as (i) Laird et al. does not disclose the use of a sample which has not been exposed to a bisulfite reagent and (ii) in the sample that the Patent Office identifies as being

equivalent to the claimed Sample B, only the amount of DNA is determined, not the amount of methylation. Consequently, steps (b) and (c) of the claimed method are neither taught nor suggested by Laird et al. Moreover, Klippel et al. and Lorincz et al. do not cure these deficiencies of Laird et al.

Accordingly, for at least the above reasons, the subject rejection should be withdrawn.

Applicants note that claims 12, 22, 27, 29, 30 have not been rejected on the basis of any prior art. Therefore, in view of the fact that the only bases under which these claims have been rejected have been overcome in this paper, Applicants respectfully request that claims 12, 22, 27, 29 and 30 be allowed at once.

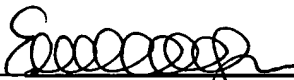
In conclusion, it is respectfully submitted that the present application is now in condition for allowance. Prompt and favorable action is earnestly solicited.

If there are any fees due in connection with the filing of this paper that are not accounted for, the Examiner is authorized to charge the fees to our Deposit Account No. 11-1755. If a fee is

required for an extension of time under 37 C.F.R. 1.136 that is not accounted for already, such an extension of time is requested and the fee should also be charged to our Deposit Account.

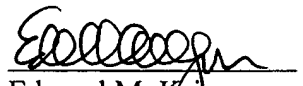
Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on April 30, 2008.


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